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Original Article
Clinical Investigation

Does primary urethral realignment improve the outcome of pediatric pelvic fracture urethral injury? A randomized controlled trial

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Abbreviations & Acronyms
MFR = maximum flow rate
PFUI = pelvic fracture urethral injury
PR = primary urethral realignment
PVR = post-voiding residue
SPC = suprapubic cystostomy

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Objective: To assess the efficacy of primary urethral realignment in the prevention of urethral stenosis and in simplifying delayed urethroplasty after complete pelvic fracture urethral injury in male children.
Methods: This randomized comparative trial included 40 boys <18 years with complete pelvic fracture urethral injury. The initial management was a primary urethral realignment in 20 boys and suprapubic cystostomy alone in the remaining 20 boys. The boys who underwent primary urethral realignment were assessed regarding the development of urethral stenosis. Boys who needed to be delayed urethroplasty in the two groups were compared regarding urethral defect length, intraoperative details, postoperative outcomes, number of procedures, and time to achieve normal voiding.
Results: Although 14 (70%) patients were able to void after primary urethral realignment, all of them developed urethral stenosis and needed delayed urethroplasty. No statistically significant difference between the two groups was found regarding urethral defect length, intraoperative details, and postoperative outcomes. Patients in the primary urethral realignment group underwent significantly more procedures ($p < 0.001$) and took a significantly longer time to achieve normal voiding ($p = 0.002$).
Conclusion: Primary urethral realignment is neither able to prevent urethral stenosis nor effective in simplifying later urethroplasty after complete pelvic fracture urethral injury in male children. It exposes the patients to more surgical procedures and a prolonged clinical course.

Key words: pediatric injury, pelvic fracture, primary urethral realignment, urethroplasty.

INTRODUCTION

Pelvic fracture in children is an uncommon event that needs a high-impact trauma to happen.[1] Moreover, pelvic fracture urethral injury (PFUI) occurs in <1% of children with pelvic fractures.[2] The devastating long-term sequelae of PFUI in the form of urethral stenosis, urinary incontinence, and erectile dysfunction emphasize the importance of providing the best management for the injured children. Because of its infrequency, the available reports on the management of PFUI in children are limited, underpowered, and controversial.[3]

The main existing controversy is about the initial management; whether primary urethral realignment (PR) yields better outcomes than suprapubic cystostomy (SPC) alone or not. Some authors recommend PR claiming that it can prevent urethral obliteration in a considerable portion of patients and minimize the difficulty of delayed urethroplasty by approximating urethral ends and bringing them into alliance.[4,5] On the contrary, some authors recommend SPC denying any benefit from PR in avoiding urethral stenosis or decreasing the length of the resultant gap.[6,7]

The lack of prospective randomized trials addressing this issue was the motive to conduct this study to compare PR and SPC in the initial management of complete PFUI in male children. We aimed to assess the efficacy of primary urethral realignment in the prevention of urethral stenosis and in simplifying delayed urethroplasty.

MATERIALS AND METHODS

This prospective randomized trial was held out in a single tertiary-care center between June 2018 and October 2021. All the surgical and endoscopic procedures were performed by three senior highly experienced urologists. The study included male children <18 years presented to the trauma unit with complete PFUI. Children with hemodynamic instability or neurological insult that prevents surgical intervention within 1 week were excluded. Also, patients with a history of previous urethral intervention or an indication of immediate repair as concomitant bladder neck or rectal injury were excluded.

The primary outcome considered on calculation of sample size was the ability of PR to prevent urethral stenosis after PFUI. Because the previously reported results in children had a very wide range (from 0% to 85%), we derived the percentage targeted to be detected from a meta-analysis of PR results in adults. The rate of prevention of urethral stenosis demonstrated by this meta-analysis was 37.2%.[8] Assuming a 35% risk reduction of urethral stenosis in the PR group versus zero% in the SPC group with 0.05 type one statistical error, a sample size of 34 cases had a statistical power of 80%. So, we decided to have 20 patients in each group (a total sample size of 40 patients).

Out of 62 boys with PFUI, 47 were eligible to be included. In the acute trauma settings, the diagnosis of complete PFUI was confirmed by retrograde urethrography (RUG), and an 8-Fr SPC was fixed percutaneously for temporary urinary diversion. Then the patients were randomized into two groups (PR group and SPC group) using the closed envelope method. Seven patients were excluded because they missed follow-up after the initial management leaving 20 patients in each group. Figure 1 presents the flow chart of patients in this study.

Patients in group A had PR within 1 week after the trauma. It was done endoscopically except for cases that had abdominal exploration for the management of other concomitant injuries. Endoscopic PR was done in a lithotomy position with special care for associated fractures. A guidewire was inserted into the previously fixed SPC tube. The suprapubic track was dilated to insert a 20-Fr working sheath through which a pediatric cystoscope was passed into the bladder neck to put a guide wire into the pelvic hematoma. Then the cystoscope was passed in a retrograde manner through the anterior urethra to retrieve the guide wire by forceps. A Foley's urethral catheter of suitable size was then passed on the guide wire and a 16-Fr SPC tube was fixed at the end of the procedure.

For open PR, a cystotomy was opened to pass a Nelaton catheter through the bladder neck and the proximal end of the distracted urethra. A Foley catheter was introduced through the external urethral meatus to pass the distal end of the distracted urethra. The tips of the two catheters were tied together and they were pulled to retrieve the Foley's catheter placing its tip and balloon inside the bladder. A 16-Fr cystostomy tube was fixed before the closure of the bladder.

Peri-catheter RUG was done 6 weeks after PR and was repeated every 2 weeks in case of contrast material extravasation. After confirmation of the absence of dye extravasation, the urethral catheter was removed and the suprapubic tube was clamped. In cases with post-voiding residue (PVR) of more than 50 mL or urinary retention, the suprapubic tube was de-clamped. If the patient had micturated freely, the suprapubic tube was removed and the patient was re-evaluated after 1 month by ultrasonography, uroflowmetry, and RUG. After one trial of endoscopic dilatation, PR was considered unsuccessful to obviate the need for urethroplasty if there was urethral stenosis on RUG or abnormal uroflowmetry. The uroflowmetry was considered abnormal when the maximum flow rate (MFR) was below the fifth percentile on the Miskolc nomogram.[9]

For patients in group B, the previously fixed SPC tube was just replaced by a 16-Fr Foley's catheter to prevent future blockage or slippage. Similarly, in children explored abdominally for concomitant injuries, a 16-Fr Foley's catheter was inserted into the bladder and secured to the abdominal wall.

Transperineal urethroplasty was done to all patients in the SPC group 3 months after the trauma and to patients with failed PR 6 weeks after the trial of endoscopic dilatation. Combined RUG and voiding cystourethrography were done before urethroplasty to measure the length of urethral defect or stenosis. The elaborate perineal approach was used with the mobilization of the bulbar urethra up to the penoscrotal junction. Midline corporeal separation, inferior wedge pubectomy, and urethral rerouting were resorted to sequentially to obtain a tension-free mucosa to mucosa anastomosis of the spatulated urethral ends. The urethral catheter was removed after urethroplasty when there was no contrast material extravasation on peri-catheter RUG. The first peri-catheter RUG was done 3 weeks after the operation and was repeated weekly as required. Follow-up was done 1, 3, and 6 months after catheter removal. Urethroplasty was considered successful if the child was voiding adequately with PVR <50 mL and normal uroflowmetry with no further intervention or only single endoscopy after urethroplasty.

The two groups were compared regarding pre-intervention data, outcomes of initial management, operative details of urethroplasty, and its outcomes (Table 1). Furthermore, we compared the two groups regarding the number of procedures done on the patients and the time taken to achieve normal voiding (Table 1). Mann–Whitney *U* test and Fisher's exact test were used for statistical analysis of quantitative and categorical variables, respectively. IBM® SPSS® Statistics version 20 was the software used for statistical analysis. The cut-off *p*-value for statistical significance was 0.05.

RESULTS

The median (range) age of the included 40 patients was 12 (3–17) years. The most common cause of trauma was motor vehicle accidents. According to the Tile classification, the most common type of pelvic fracture was type A (Table 1). Associated injuries were encountered in 26 patients with lower limb long bone fractures representing the most common associated injury (Table 2). There was no statistically significant difference between the two groups regarding the age, type of pelvic fracture, or mechanism of trauma (Table 1).

All PR procedures were successful and did not result in specific complications such as pelvic abscess, iatrogenic

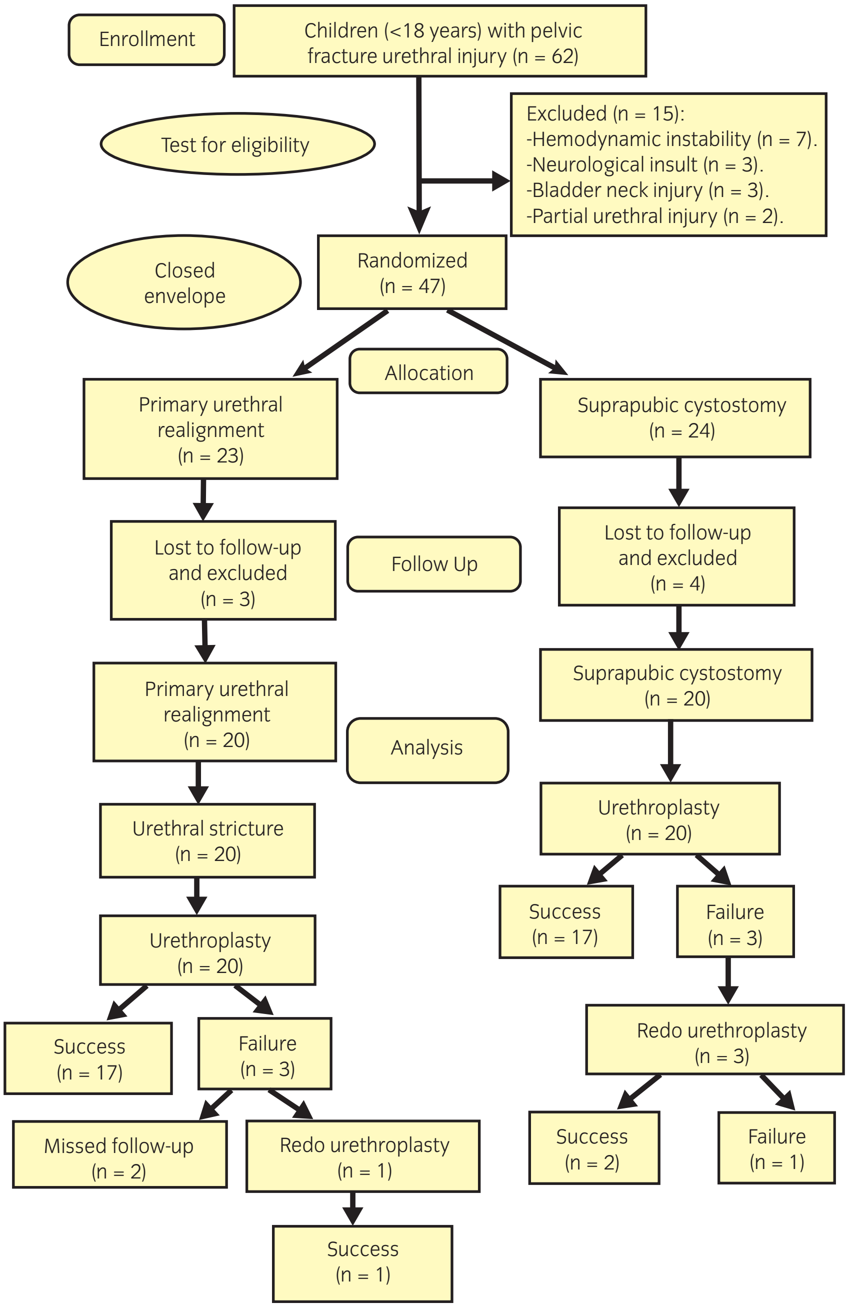

FIGURE 1 Flow chart of the patients included in the trial.

urethral stenosis, or fistula. Although 14 (70%) patients were able to void after PR, all of them failed to establish a normal uroflowmetry with evident abnormalities (stenosis and/or malalignment) on RUG (Figure 2). The median (range) of their MFR was 2.5 (0.6–5.3) mL/s. Therefore, PR failed to eliminate the need for urethroplasty in any case and all the patients included in the study were indicated for urethroplasty. The length of urethral defect or stenosis was assessed in 37 patients due to failure to perform combined RUG and voiding cystourethrography in three cases (one in the PR group and two in the SPC group). There was no statistically significant difference between the two groups regarding the radiological length of the urethral defect (Table 1).

Transperineal urethroplasty was done on all the included patients. The median (range) operative time was 210 (120–300) minutes and the median (range) estimated blood loss was 525 (250–1200) mL. Two intraoperative complications occurred in the form of corpus cavernosum injury in one patient in the PR group and seromuscular rectal injury in one patient in the SPC group. The median (range) hospital stay was 4 (3–8) days. Postoperative complications were encountered in 16 (40%) patients (Table 3).

Transperineal urethroplasty succeeded in 34 (85%) cases. Of the failed six cases (three in each group), four patients had urinary retention with complete urethral obliteration on urethroscopy and two had abnormal uroflowmetry with

TABLE 1 Comparison between primary urethral realignment and suprapubic cystostomy in the initial management of complete pelvic fracture urethral injury in male children.

	All patients $n = 40$	Group A[a] $n = 20$	Group B[b] $n = 20$	p value
Pre-intervention data				
Age in years[c]	12 (3–17)	12.5 (4–17)	12 (3–16)	0.522
Type of pelvic fracture[d]				0.422
Type A	18 (45%)	10 (50%)	8 (40%)	
Type B	5 (12.5%)	1 (5%)	4 (20%)	
Type C	17 (42.5%)	9 (45%)	8 (40%)	
Mechanism of trauma[d]				0.913
Motor vehicle accident	23 (57.5%)	12 (60%)	11 (55%)	
Compression trauma	9 (22.5%)	4 (20%)	5 (25%)	
Fall from height	8 (20%)	4 (20%)	4 (20%)	
Outcomes of initial management				
Need for urethroplasty[d]	40 (100%)	20 (100%)	20 (100%)	1
Urethral defect length in cm[c]	3 (1.2–5.3)	3 (1.2–5.3)	3.5 (1.5–5)	0.206
Operative details of urethroplasty				
Operative time in minutes[c]	210 (120–300)	200 (120–300)	217.5 (135–280)	0.871
Estimated blood loss in mL[c]	525 (250–1200)	600 (300–1150)	475 (250–1200)	0.102
Elaborate perineal approach[d]				
Midline corporeal separation	36 (90%)	17 (85%)	19 (95%)	0.604
Inferior pubectomy	32 (80%)	17 (85%)	15 (75%)	0.694
Urethral rerouting	1 (2.5%)	1 (5%)	0	0.999
Intraoperative complications[d]	2 (5%)	1 (5%)	1 (5%)	1
Outcomes of urethroplasty				
Postoperative complications[d]	16 (40%)	7 (35%)	9 (45%)	0.747
Hospital stay in days[c]	4 (3–8)	4.5 (3–8)	4 (3–7)	0.441
Success[d]	34 (85%)	17 (85%)	17 (85%)	1
Maximum flow rate in mL/s[c]	12.3 (1.5–27.9)	12.6 (9.2–18.6)	11.2 (1.5–27.9)	0.135
Continence status[d]				0.573
Continent	24 (70.6%)	13 (76.5%)	11 (64.7%)	
Mild incontinence	9 (26.5%)	4 (23.5%)	5 (29.4%)	
Severe incontinence	1 (2.9%)	0	1 (5.9%)	
Number of procedures[c]	3 (2–6)	3.5 (3–6)	2 (2–4)	<0.001*
Time to achieve normal voiding in days[c]	209 (116–592)	232 (142–592)	176 (116–476)	0.002*

[a]Primary realignment group. [b]Suprapubic cystostomy group. [c]Quantitative variables presented as median (range) and analyzed by Mann–Whitney *U* test. [d]Categorical variables presented as frequency (percentage) and analyzed by Fisher's exact test. *Statistically significant.

TABLE 2 List and frequencies of concomitant injuries associated with complete pelvic fracture urethral distraction injury in male children.

Concomitant injury[a]	Frequency (%)[b]
Lower limb long bone fracture	18 (45%)
Degloved skin injury	2 (5%)
Hepatic tear	2 (5%)
Splenic tear	2 (5%)
Common bile duct injury	1 (2.5%)
Testicular hematoma	1 (2.5%)
Amputated limb	1 (2.5%)
Shoulder dislocation	1 (2.5%)
Diaphragmatic tear	1 (2.5%)
Rib fracture	1 (2.5%)

[a]Some patients had more than one concomitant injury. [b]Total number of patients = 40.

significant PVR even after endoscopic dilatation. Later on, two of them missed follow up and four underwent redo urethroplasty that succeeded in three (Figure 1). Postoperative uroflowmetry was done to 35 cases because four patients had urinary retention and one patient had incontinence that prevented getting an adequate voided volume. The median (range) of post-urethroplasty MFR was 12.3 (1.5–27.9) mL/s.

Regarding the continence state after successful urethroplasty, nine patients had mild stress urinary incontinence (no or one protection pad daily) and one patient had severe incontinence (more than one pad daily). There was no statistically significant difference between the two groups regarding intraoperative details or outcomes of urethroplasty (Table 1). However, significant difference between the two groups was only found regarding the number of procedures ($p < 0.001$) and the time taken to achieve normal voiding ($p = 0.002$). Patients in the PR group required significantly more procedures and longer time (Table 1).

DISCUSSION

The options for initial management of complete PFUI are primary reconstruction, PR, and primary drainage by SPC only.[3] In females and cases with concomitant bladder neck or rectal injuries, primary reconstruction is indicated.[10] Otherwise,

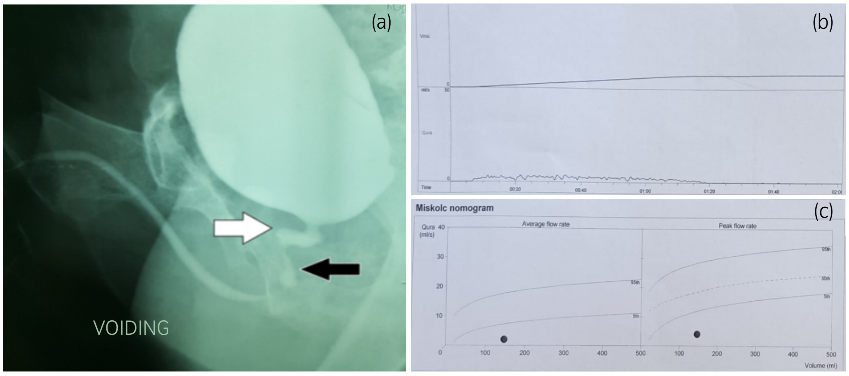

FIGURE 2 Follow-up evaluation (1 month after removal of urethral catheter) of an 8-year-old boy who had primary realignment as initial management of pelvic fracture urethral injury. (a) Voiding cysto-urethro-gram showing urethral malalignment (white arrow) and irregular urethral stenosis (black arrow). (b) Uroflowmetry showing flat curve, voided volume of 147 mL, low maximum flow rate (3.5 mL/s), low average flow rate (2 mL/s), prolonged voiding time (95 s), and prolonged flow time (72 s). (c) Miskolc nomogram showing that both average and maximum flow rates are below the 5th percentile.

TABLE 3 Complications of delayed urethroplasty in male children with complete pelvic fracture urethral distraction injury.

	Group A[a] n = 20	Group B[b] n = 20	Total n = 40
Intraoperative complications			
Corpus cavernosum injury	1 (5%)	0	1 (2.5%)
Seromuscular rectal injury	0	1 (5%)	1 (2.5%)
Postoperative complications[c]			
Fever	5 (25%)	6 (30%)	11 (27.5%)
Wound infection	1 (5%)	3 (15%)	4 (10%)
Hematuria	2 (10%)	1 (5%)	3 (7.5%)
Wound urinary leakage	1 (5%)	0	1 (2.5%)
Epididymo-orchitis	0	1 (5%)	1 (2.5%)
Marked penile edema	1 (5%)	0	1 (2.5%)

[a]Primary urethral realignment group. [b]Suprapubic cystostomy group. [c]Some patients had more than one complication.

primary reconstruction is not recommended because it results in extensive blood loss and high rates of stenosis, incontinence, and erectile dysfunction.[10] For the rest of the cases, primary drainage by SPC alone inevitably results in urethral obliteration and mandates a delayed urethroplasty.[11]

PR was supposed to prevent urethral stenosis after PFUI by allowing urethral mucosal regeneration alongside the catheter. This postulate had been challenged early by a controlled experimental study that revealed no epithelization of the mucosal gap after sutureless realignment of the transected prostato-memberanous urethra in 11 dogs.[12] Despite these old robust results, PR continued to have its share in practice as evidenced by the mass of literature addressing the procedure.[13,14]

To the best of our knowledge, the literature lacks any prospective randomized comparison between PR and SPC in the initial management of PFUI in male children. Even in adults, the current evidence regarding this topic is derived from a systematic review of non-randomized studies (Level 3A). Only there is a published research protocol of a multi-institutional prospective study planning to compare the two lines of initial management in adult men >18 years,[15] but its final results have not been published yet. The present study will be the first Level 2 evidence in this field. Nevertheless, although the findings of our study are generalizable to patients meeting our inclusion criteria, they cannot be generalized to boys sustaining partial PFUI.

Previous retrospective reports about PR as initial management of PFUI in male children had variable and contradicting results. This is due to variations in the inclusion criteria, technique of PR, and definition of success. Similar to the results of the current study, Podesta et al.[6] reported 100% failure to avoid urethral stenosis in 10 boys. Also, Wang et al.[16] reported five boys that needed urethroplasty after endoscopic realignment, but they did not mention if there were other patients that had successful PR.

On the other hand, Avanoglu et al.[17] reported a 50% success rate for PR, but they included a girl as well as patients with isolated bladder neck injury. A similar success rate was reported by Nerli et al.[18] in a series of 12 boys. However, five patients in this series had open realignment with suture anastomosis which is rather considered as primary repair. Balkan et al.[4] reported even a higher success rate approaching 85%. Nevertheless, they included patients with partial injuries. Furthermore, most of the patients in whom PR was considered successful required multiple urethral dilatations or urethrotomies to avoid urethroplasty. Onen et al.[5] and Boone et al.[19] also reported results in favor of PR, but the definition of success and the need for further interventions were not clearly mentioned.

No doubt that a considerable percentage of the boys who underwent PR as initial management of PFUI retain the ability to void as found in our results. Yet, the efficiency and normality of voiding through the fibrous tract that was developed around the catheter by spontaneous healing process should be questioned. None of the previously mentioned studies reported the urine flow rates after PR. Actually, it is a tough task to define the normal MFR for a child due to great variability of body size, urethral caliber, bladder capacity, and voided volume.[9] We used the Miskolc nomograms[9] as an objective tool for the evaluation of urine flow rates of the children included in this study. None of the boys who were able to void after PR demonstrated an MFR above the 5th percentile.

PR seems to do better in adult men as regards prevention of urethral stenosis after PFUI with an absolute risk reduction of 37.2%.[8] The anatomical peculiarities of the posterior urethra in male children affect the nature of the injury and subsequently affect the efficacy of PR in the prevention of stenosis. The underdeveloped prostate and the delicate nature of the puboprostatic ligament in children increase the probability of complete urethral disruption, a more proximal site of injury, and higher displacement of the proximal urethra.[18,20] The higher incidence of partial PFUI in adults improves the results of PR. Furthermore, the higher displacement of the proximal urethral end and the absence of prostatic support to the aligned urethra render PR to be less efficient in approximating the sheared urethral ends in children. It is worth mentioning that PR in children is technically more difficult than in adults and needs considerable surgical experience.

Another proposed benefit of PR is that it may decrease the gap between the urethral ends which can simplify the later anastomotic urethroplasty. In the same line as our results, two previous studies found no difference between PR and SPC regarding the length of the stenosis.[6,7]

Conventionally, a combined abdominoperineal approach had been preferred to a transperineal approach for the reconstruction of PFUI in children.[21,22] This was advocated by the higher anatomical level of distraction, the greater urethral displacement, and the narrow perineal field in children. However, a more recent series—in agreement with our results—reported that anastomotic urethroplasty can be achieved through an elaborate transperineal approach in most of cases with success rates ranging from 80 to 93%.[16,23,24] The abdominoperineal and posterior sagittal approaches should be reserved for complicated PFUI associated with skeletal abnormalities or fistulae to the bladder base or rectum.[20,25]

Regarding the outcomes of urethroplasty after either PR or SPC alone in male children, several retrospective studies did not find any difference in the success rate.[6,17] Tausch and Morey[7] in their series with unidentified age group reported a significantly lower success rate of urethroplasty after PR. In our cohort, even the operative time and the need for sequential steps of elaborate perineal approach did not show a significant difference. Although not statistically significant, blood loss was somewhat higher in the PR group which may reach significance with a larger sample size. This can be attributed to the effect of realignment and endoscopic maneuvers on the propagation of scar formation and increasing periurethral fibrosis.[26] All this data refutes the concept of easier urethroplasty after PR.

Incontinence after PFUI is caused by neglected bladder neck injury or neurogenic bladder neck dysfunction.[27] So, it is related to the severity of the initial trauma regardless of whether PR or SPC only was performed as initial management.[6] However, balloon traction during PR can cause ischemic damage to the bladder neck resulting in incontinence. As we did not apply catheter traction in PR cases, the initial management of PFUI did not affect the continence status.

About 40%–50% of boys that sustained PFUI suffer from erectile dysfunction during adulthood due to vasculogenic and/or neurogenic etiologies.[28] Lateral prostatic displacement and long urethral gap were identified as predictors for erectile dysfunction after PFUI in children.[28] In the present study, this issue was not evaluated due to the lack of an objective tool for its assessment during the limited follow-up period of the included children.

The present trial projects light over a crucial difference between the two lines of initial management of PFUI in male children; PR leads to a prolonged clinical course with multiple additional procedures. Similar results were reported after PFUI in adults.[29,30] While patients go for a straightforward urethroplasty a few months after SPC, PR converts the acute well-defined injury to a chronic unstable disease. This may have psychological and social drawbacks, in addition to the costs of increased hospital visits, diagnostic procedures, and operative interventions. Moreover, the fact that the child can void after PR may result in neglecting a hazardous urethral stenosis. For these reasons, a close follow-up and low threshold for prompt referral for reconstructive surgery are highly recommended after PR.[31] In conclusion, PR is neither able to prevent urethral stenosis nor effective in simplifying later urethroplasty after complete PFUI in male children. It exposes the patients to more surgical procedures and a prolonged clinical course. Primary drainage by SPC alone should be the standard initial management of such cases.

AUTHOR CONTRIBUTIONS

Taha M. Taha: Conceptualization; methodology; data curation; supervision; formal analysis; validation; project administration. **Mohamed O. Ali:** Conceptualization; methodology; software; data curation; formal analysis; validation; writing—original draft; project administration; resources. **Ahmed A. Shahat:** Conceptualization; methodology; software; data curation; supervision; formal analysis; writing—review & editing; project administration; writing—original draft. **Medhat A. Abdalla:** Conceptualization; methodology; supervision; validation; visualization; project administration. **Hisham M. Hammouda:** Conceptualization; methodology; data curation; supervision; formal analysis; validation; visualization; investigation; project administration; writing—review & editing. **Hosny M. Behnsawy:** Methodology; software; data curation; formal analysis; investigation; writing—original draft; writing—review & editing; resources.

CONFLICT OF INTEREST STATEMENT

No conflict of interest.

APPROVAL OF THE RESEARCH PROTOCOL BY AN INSTITUTIONAL REVIEWER BOARD

Approved by our Institutional Committee of Ethics (No. 17200182).

INFORMED CONSENT

Written informed consent was obtained from parents or care giver of each participant.

REGISTRY AND THE REGISTRATION NO. OF THE STUDY/TRIAL

Approved by Clinical Trial Registry (No. NCT03468387) verified April 2018 on ClinicalTrials.gov.

ANIMAL STUDIES

N/A.

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Editorial Comment

Editorial Comment on the article titled "Does primary urethral realignment improve the outcome of pediatric pelvic fracture urethral injury? A randomized controlled trial"

The key in the management of the acute phase of pelvic fracture urethral injury (PFUI) is prompt urinary drainage by the placement of a suprapubic tube (SPT) or primary realignment (PR) of the urethra over a urethral catheter. Although it has long been believed that PR can reduce the risk of developing urethral obstruction and make subsequent delayed urethroplasty easier, it can be associated with increased stenosis complexity by direct urethral damage and a prolonged treatment period.[1]